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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/028,514 02/23/98 GORFIEN

S 0942.4110002

EXAMINER

HM22/0801

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ART UNIT

PAPER NUMBER

1651

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08/01/01

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/028,514

Applicant(s)

Gorfien et al.

Examiner

Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 7, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-37, 73-77, 79-82, 106-112, 140, and 143-160 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-37, 73-77, 79-82, 106-112, 140, and 143-160 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

Art Unit: 1651

Claims 1-37, 73-77, 79-82, 106-112, 140 and 143-160 are presented for reconsideration on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Also receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicants' response to the request for clarification of the Information Disclosure Statements is appreciated and attached copies of the PTO-1449 Forms to the response are noted.

2. Claims 1-29, 79, 140, 154 and 158 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Israel, (U.S. Patent No. 5,318,898), previously cited in the Office action of December 23, 1999, for those reasons of record, note page 4 of the Office action filed November 6, 2000.

3. The claims are similar to the disclosure of Israel and furthermore, this reference does teach suspension culturing of cells in a culture medium containing known ingredients (i.e. chemically defined culture medium). Therefore, the claims are considered to be anticipated by the cited disclosure. The claim limitations which are silent in Israel are inherent to the teachings of the cited reference. However, in the alternative that there is some unidentified characteristics for which provides for some difference between that which is claimed and the teachings of Israel then such difference is considered to be so slight as to render the claimed invention obvious. It is

Art Unit: 1651

further important to note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' claimed method(s) differ(s) and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Applicants' arguments filed May 7, 2001, have been fully considered but they are not persuasive. The argument that Israel fails to teach a chemically defined medium is not deemed persuasive since such basal medium types disclosed by Israel (i.e. RPMI) are well recognized to be chemically defined. Thus, although the specific terms "chemically defined" may not be recited in the cited disclosure of Israel the teachings of the various medium types such as Dulbecco's MEM, RPMI 1640 and other media are known and recognized to encompass the meaning "chemically defined". Applicants' reliance of the absence of the teaching of "chemically defined" is misguided and not regarded as evidence that the teaching is absent from Israel. Thus, the rejection is maintained.

4. Claims 30-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Israel, discussed above, in view of World Patent 92/05246, both cited of record in the instant case.

Note the previous Office action of November 6, 2001, pages 4-5.

Applicants' arguments filed May 7, 2001, have been fully considered but they are not persuasive. In response to Applicants' argument that a chemically defined culture medium is not disclosed by Israel which is not deemed persuasive because the limitation of "chemically defined" taught by Israel as discussed above. Furthermore, the combination was based upon the

Art Unit: 1651

usefulness of similar media types for other cell types other than Chinese Hamster Ovary (CHO) cells. The rejection was not based upon the addition of yeast hydrolysate which Applicants allege is a component of the cited World Patent. Also Israel clearly teaches the medium to comprise at least one polyanionic or polycationic compound (i.e. dextran sulfate). Thus, in response to applicant's argument that yeast hydrolysate is used and is not a chemcially defined mixture is not regarded as an issue when Israel alone provides the teaching of a chemically defined culture medium and the WO patent shows the usefulness of serum free media for all types of mammalian cells, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Therefore, this rejection is maintained.

5. Claims 73-77 and 79-82 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Israel in view of the World Patent, both discussed above, and Inlow et al. also cited of record. Note the previous Office action of November 6, 2001, pages 5-6.

Applicants' arguments filed July 28, 2000, have been fully considered but they are not persuasive since Israel does indeed teach a chemically defined cell culture medium and cultivating a mammalian cell in suspension in vitro, as discussed above. Further, Inlow et al. clearly teach a serum free culture media useful for culturing viral components as claimed herein. Note column 1, line 21, of Inlow et al. It is clear or at least suggested in order for a culture medium to be serum free its components must be known and such media would suggest a

Art Unit: 1651

chemically defined culture medium. Also insect cells are considered to be animal cells and one of skill would have expected successful results cultivating in vitro cells of both mammalian and insectal origin on similar culture medium. Thus, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, Applicants' arguments are not deemed convincing and the rejection is maintained.

6. Claims 106, 143-149, 155 and 157-160 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Keen et al., previously cited of record in the Office action of December 23, 1999, for those reasons set forth in the Office action of November 6, 2000, see page 6.

Claims and Keen et al. are discussed of record in the case.

The claims are so similar to the disclosure of Keen et al. that they are considered to be anticipated by the teachings of the cited reference. However, in the alternative that there are some unidentified characteristics for which applicants have not set forth herein (i.e. other than suspension culture and chemically defined culture medium), and such characteristics provide for some difference then the difference is considered to be so slight as to render the claims obvious over the cited reference. Note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine what these characteristics might be in order to establish

Art Unit: 1651

some difference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants. The ions of zinc and iron as well as the concentrations are clearly disclosed by Keen as being useful in culture medium for purposes of culturing mammalian cells as well as the absence of insulin. Thus, to replace one for the other is inherent to the cited disclosure or at least obvious to one of skill in the art.

Applicant's arguments filed May 7, 2001, have been fully considered but they are not persuasive. The argument that the reference teaches only media containing insulin is not deemed persuasive since the medium of Table 1, at columns 4-5, does not include insulin per se. Therefore, the absence of insulin is taught by the reference or the motivation to exclude it therefrom is clearly obvious to one of skill in the art. Thus the arguments are not deemed persuasive.

7. Claims 150-153 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al. discussed of record.

Applicant's arguments filed May 7, 2001, have been fully considered but they are not persuasive. Keen et al. is argued by Applicants as allegedly explicitly teaching the requirement for insulin, however, as discussed above at Table 1, columns, 4-5, all lines, no insulin is disclosed in the medium A and it is thus, not explicitly taught as argued by Applicants. Furthermore, to vary concentrations of chelators is clearly within the purview of an ordinary artisan as is the use of various media types for cultivation of cells. The claims are prima facie

Art Unit: 1651

obvious over the cited reference and the standard of obviousness has been well applied with the cited reference. This rejection is maintained for reasons of record.

8. Claims 106-112, 143-153 and 156-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al. in view of Israel and Inlow for those reasons of record.

Applicant's arguments filed May 7, 2001, have been fully considered but they are not persuasive. The arguments that this rejection should be withdrawn because Keen et al. teaches insulin is necessary and because Inlow relates only to insect cells are not persuasive for those reasons noted above. Keen et al. do indeed teach that chelates can replace transferrin and insulin or at least suggests the replacements thereof. Thus, the combination of these prior art references would not have led one of skill away from using chelates in place of transferrin and/or insulin etc. Further, to vary media types that are well known in the art is clearly within the purview of an ordinary artisan, as noted above. Therefore, the desirability in the art to use chelates is clearly disclosed and to vary their concentrations is well within the knowledge of those of skill in this art, as discussed *supra*. This rejection, is hereby being maintained for those reasons above and for those of record. In addition, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Art Unit: 1651

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

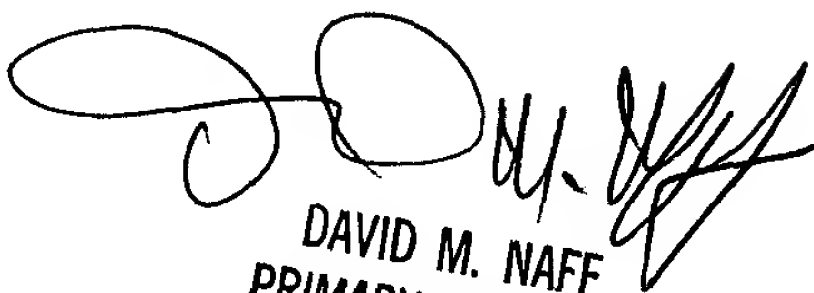
Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Deborah K. Ware

Art Unit 1651

July 29, 2001


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651